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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/699,882	11/04/2003	Robert C. Brunham	1038-1274 MIS:jb	7783

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EXAMINER	
PORTNER, VIRGINIA ALLEN	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 10/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/699,882	BRUNHAM ET AL.	
	Examiner	Art Unit	
	Ginny Portner	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *29-40* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-40* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 29-32, 34-40 are pending.

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 29-32, 35-40 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,676,949 B2. Although the conflicting claims are not identical, they are not patentably distinct from each other because the allowed species anticipates the instantly claimed genus of methods that only comprise a single methods step and administers any Chlamydia encoded protein or fragment thereof, while the allowed species is directed to the administration of a species of Chlamydia encoded protein, specifically Chlamydia MOMP protein, along with a second administration of expressed protein composition .

The allowed species anticipates the instantly claimed genus of methods.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

4. Claims 29, 35,37-40 are rejected under 35 U.S.C. 102(e) as being anticipated by Gurtiss III (US Pat. 5,389,368).

Gurtiss, III disclose a method of stimulating an immune response caused by a pathogenic microorganism, wherein the method comprises (see Gurtiss, col. 12, lines 49-64):

administrating an attenuated bacteria that is harboring a heterologous nucleic acid molecule that encoded for a second pathogenic microorganism, wherein expression of the heterologous nucleic acid stimulates a secretory immune response to stimulate the lymphoid cells of the GALT or BALT.

Incorporation of the nucleic acid molecule into the attenuated bacteria is accomplished through the use of plasmid, phage or cosmid vectors (see col. 11, lines 17-47, especially lines 33-37). Gurtiss states: "The recombinant DNA is packaged within a phage such as transducing phage or cosmid vectors. Once the recombinant DNA is in the carrier cell, it may continue to exist as a separate piece (generally true of complete transmitted plasmids) or it may insert into the host cell chromosome and be reproduced with the chromosome during cell division." (Gurtiss, col. 11, lines 17-47). The attenuated bacteria is a live attenuated Salmonella, Escherichia or Salmonella-Escherichia hybrid strain that expresses a gene product from *Chlamydia trachomatis* **(see Gurtiss, claim 6)**.

A number of attenuated bacteria are taught as being useful in immunizing a host and include: Salmonella, E.coli and Salmonella-E.coli hybrids. (see Gurtiss, claim 1 and col. 6, lines 10-15).

Administration is accomplished by any one of a number of routes, to include mucosal administration of the attenuated bacteria, specifically : oral, gastric, aerosol (nasal, see col. 10, lines 63) or intravaginal administration of the attenuated bacteria. The preferred embodiment is through intranasal administration (see Gurtiss, col. 10, lines 60-68 and col. 11, lines 1-16; claim 9).

Gurtiss, III discloses an attenuated Salmonella that serves to carry the encoded nucleic acid molecule in a host cell for immunizing a host (see col. 34, lines 32-39; col. 35, line 8), and provides sight directed vector delivery system to host cells (see col. 8, lines 47-51; col. 7, lines 27-29). The attenuated Salmonella minimizes possible random adsorption of nucleic acid molecules, maximizes stimulation of a mucosal immune response (Salmonella binds to GALT and BALT cells) in mucosal host cells and can stimulate an immune response to Salmonella, as

well as the heterologous protein expressed in the host cells. The reference inherently anticipates the instantly claimed invention.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 30-32, 34, and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gurtiss, III (US Pat. 5,389,368) as applied to claims 29,35,37-40 above, in view of Brunhan (WO98/02546).

See discussion of Gurtiss above. The reference teaches a method of stimulating an immune response in a host that comprises initially administering an attenuated bacteria harboring a nucleic acid molecule encoding a Chlamydial antigen, but differs from the instantly claimed invention by failing to show the use of a nucleic acid encodes a MOMP encoded protein, wherein the MOMP protein is from trachomatis, has a cytomegalovirus promoter , the plasmid vector is pcDNA3.

Brunham teaches the nucleic acid that encodes a protective MOMP or MOMP fragment of Chlamydia, wherein the MOMP nucleic acids were obtained from Chlamydia trachomatis, and incorporated into pcDNA3 (see page 25, Table 2), teaches the use of a cytomegalovirus

promoter in association with the MOMP nucleic acids (see claim 4, 6, 16) in an analogous art for the purpose of teaching nucleic acid sequences that encode protective Chlamydia proteins for stimulating a host immune response.

Therefore, it would have been obvious to the person of ordinary skill in the art at the time the invention was made to modify the attenuated Salmonella, of Gurtiss to include the nucleic acid that encodes for a Chlamydia protective MOMP protein of Brunham because Gurtiss teaches that through administration of a live attenuated bacteria that encodes a protective protein a host is stimulated to produce an immune response directed against the expressed gene product and with a subsequent administration of purified protein, an enhanced secretory immune response is obtained.

The person of ordinary skill in the art would have been motivated by the reasonable expectation of success of obtaining an immune response using the method and attenuated bacteria of Gurtiss with the nucleic acid of Brunham that encodes a protective MOMP protein of Chlamydia, because Gurtiss teaches that Chlamydia is a pathogen that causes venereal diseases and eye infections and the attenuated bacteria is capable of expressing a recombinant gene product, wherein use of a nucleic acid molecule that encodes a protective MOMP protein results in stimulating an immune response against the Chlamydia MOMP protein .
In the absence of unexpected results, Gurtiss in view of Brunham obviates the now claimed invention.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ginny Portner whose telephone number is (571) 272-0862. The examiner can normally be reached on 7:30-5:00 M-F, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Vgp
October 15, 2004

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